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Pesticide Fact Sheet Number 125: Mancozeb

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Pesticide Fact Sheet

Name of Chemical: MANCOZEB
Reason for Issuance: REGISTRATION STANDARD
Date Issued: APRIL, 1987
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DESCRIPTION OF CHEMICAL

Generic Name: Manganese ethylene bisdithiocarbamate
Common Name: Mancozeb
Trade Name: Dithane® M-45, Manzate® 200, Fore®
EPA Shaughnessy Code: 014504
Chemical Abstracts Service (CAS) Number: 8018-01-7
Year of Initial Registration: 1967
Pesticide Type: Fungicide (with minor insecticide use)
Chemical Family: Ethylene bisdithiocarbamate (EBDC)
U.S. and Foreign Producers: Rohm and Haas produces a
formulating intermediate;
E.I. DuPont deNemours Co.
produces mancozeb for its
own end-use products

USE PATTERNS AND FORMULATIONS

Application Sites: Terrestrial food and nonfood crops;
aquatic (food); greenhouse (nonfood); forestry;
outdoor domestic.
Major Crops Treated: Apples, potatoes, and tomatoes. Mancozeb
is also used on approximately 80 percent of the onion acreage
in the United States.
Formulation Types Registered: 80 percent active ingredient (a1)
formulating intermediate; dust, wettable powder, flowable
concentrate, and granular end-use products.
Methods of Application: Foliar applications by aerial or
ground equipment. For ground equipment, mancozeb

suspensions typically are made from a wettable powder or flowable concentrate that is applied by means of air blast sprayers or tractor-mounted boom sprayers. Dust formulations are typically applied by means of truck- or tractor-drawn duster or aerial equipment.

Treatment of the seeds may be accomplished by commercial seed treatment equipment by seed companies or by addition to the planter box at the farm site. Mancozeb may be used as a spray furrow treatment of soil at planting of onion sets. For treatment of surfaces of potato cut seed pieces or whole tuber seed pieces, mancozeb is applied by means of dip tanks or dusting equipment mounted over the seed pieces on a conveyor belt.

Application Rates: Rates range from 0.4-3.3 lb/100 gal. or 0.6-19.06 lb ai/A for foliar application (high rates are for turf use rather than food crops); 0.04-4.32 lb/100 lb. of seed; 0.78-27 lb/100 gal for preplant dip treatments and 2.4 lb/A for soil applications. Multiple applications may be made during the growing season.

Usual Carrier: Water

SCIENCE FINDINGS

Summary Science Statement: The major toxicological concern from exposure to mancozeb is the hazard to the human thyroid from presence of ethylenethiourea (ETU), a contaminant, degradation product, and metabolite present in mancozeb and other EBDC products. ETU is an acknowledged goitrogen, teratogen and oncogen. Additional chronic studies of mancozeb are required for further evaluation. Available data indicate that mancozeb itself is not a primary developmental toxicant or teratogen, however, an additional teratology study with mancozeb is required before its teratogenicity can be fully assessed.

Available data are not adequate to assess the environmental fate of mancozeb. However, studies do indicate that ETU has the potential to leach. A complete assessment of the environmental fate, including the potential for groundwater contamination, from the use of mancozeb products will be undertaken when data are available.

Available data are insufficient to completely evaluate the ecological effects of mancozeb. Based on available data, mancozeb is no more than slightly toxic to avian wildlife on an acute basis; is highly toxic to warmwater fish; and appears to be at least moderately toxic to coldwater fish.

Chemical Characteristics: Only limited product chemistry information is available, as follows:

Physical state: Solid at room temperature, decomposes when heated.

Empirical Formula: $(C_4H_6MnN_2S_4) \times (Zn)_y$

Molecular Weight: $(265.3) \times +(65.4)y$

Toxicology Characteristics:

Acute Toxicity^{1/}:

Oral Toxicity: 4500 mg/kg, Category III

Dermal Toxicity: > 5000 mg/kg, Category III

Inhalation Toxicity: > 5.14 mg/L, Category IV

Eye Irritation: Primary Irritation Score (PIS) - 2.3, Category III

Skin Irritation: PIS - 0.5, Category IV

Dermal Sensitization: Study required

Subchronic Toxicity:

Oral (rats): No observed effect level (NOEL) for kidney effects - 60 ppm (3.5 mg/kg/day, males; 4.4 mg/kg/day females)

NOEL for thyroid effects - 125 ppm (7.9 mg/kg/day, males; 9.2 mg/kg/day, females)

Oral (dogs): NOEL for systemic effects - 100 ppm (3.0 mg/kg/day, males; 3.4 mg/kg/day, females)

NOEL for thyroid effects - 1000 ppm (29 mg/kg/day for both sexes)

Dermal: Studies required

Inhalation: NOEL for systemic effects - 20 mg/m³

NOEL for thyroid 80 mg/m³

Major Routes of Exposure: Dermal and inhalation

^{1/}Toxicity Categories are discussed in 40 CFR 162.10.

Chronic Toxicity:

Chronic Toxicity: Studies required
Oncogenicity: Studies required

Teratology: Maternal toxicity: NOEL - 32 mg/kg/day;
Lowest effects level (LEL) - 128
mg/kg/day (decreased body weight)

Fetal toxicity: NOEL - 128 mg/kg/day;
LEL - 512 mg/kg/day (increased
resorptions)

Teratogenic effects: NOEL - 128
mg/kg/day; LEL - 512 mg/kg/day
(dilated ventricles, spinal cord
hemorrhage, delayed/ incomplete
ossification of skull and ribs);
A/D Ratio: $32/128 = 0.252/$

Reproduction: Study required

Mutagenicity: Negative - bacterial and in vitro mammalian
cell systems, chromosome damage
in vivo and in mammalian cell
transformation

Positive - sister-chromatid exchanges in CHO
cells in vitro

Physiological and Behavioral Characteristics

Mechanism of Pesticide Action: Mancozeb inhibits enzyme
activity by complexing with metal-containing enzymes
including those involved with the production of adenosine
triphosphate (ATP).

Metabolism: Mancozeb appears to be rapidly absorbed from
the gastrointestinal tract, distributed to target organs
and excreted almost totally by 96 hours. The major
metabolite is ETU, comprising almost 24% of the bio-
available dose in urine and bile. ETU residues in
the thyroid and the liver were less than 1 ppm and
were non-detectable after 24 hours.

Environmental Characteristics:

Hydrolysis: Mancozeb degrades with a half-life of 1 to 2
days at pH 5, 7, and 9. ETU is stable to hydrolysis at
pH 5 and 7 and is very slowly hydrolyzed at pH 9.

Anaerobic Aquatic Metabolism: Mancozeb and ETU declined
with half-lives of 92 days and 29 to 35 days, respectively.

2/An A/D Ratio of less than 1 indicates that developmental
toxicity may be ascribed to secondary effects of maternal
toxicity

Environmental Fate/Groundwater Concerns: Available studies indicate that ETU has the potential to leach. A complete assessment of the environmental fate, including the potential for groundwater contamination, from the use of mancozeb products will be undertaken when data are available.

Exposure During Reentry Operations: Mancozeb is registered for use on crops which may involve substantial exposure to residues of the pesticide. Because ETU has demonstrated evidence of oncogenicity, mutagenicity, teratogenicity and thyroid effects and mancozeb has caused thyroid effects, reentry data are required. Until these data are received and evaluated, a 24-hour reentry interval is imposed.

Ecological Characteristics:

Avian Oral Toxicity:

Japanese Quail	- > 6400 mg/kg/day
European Sparrow	- 3000-6000 mg/kg/day
English House Sparrow	- 1500 mg/kg/day
Mallard Duck	- > 6400 mg/kg/day

Freshwater Fish Toxicity:

Bluegill sunfish	- 1.54 ppm
Rainbow trout	- 0.46 ppm
Daphnia magna	- 0.58 ppm

Tolerance Assessment:

Tolerances Established: Tolerances, expressed as zinc ethylene bisdithiocarbamate, have been established for residues of mancozeb in a variety of raw agricultural commodities and meat byproducts (40 CFR 180.176 and 40 CFR 180.319), and in processed food (21 CFR 193.460) and feed (21 CFR 561.410).

Results of Tolerance Assessment: The toxicology data for mancozeb are insufficient to determine an Acceptable Daily Intake (ADI) or whether the toxicity observed in the studies is due to mancozeb or ETU.

There are no acceptable chronic studies on which to calculate an ADI, therefore, a subchronic study has been used to calculate a Provisional ADI (PADI). Because a subchronic study was used, an uncertainty factor of 1000 (rather than 100 used with chronic studies) was employed. The PADI for mancozeb is 0.003 mg/kg/day based on the 90-day dog feeding study with a NOEL of 3 mg/kg/day.

The theoretical maximum residue contribution (TMRC), based on the assumption that 100 percent of each crop is treated and contains residues at the tolerance levels, is 0.028 mg/kg/day or approximately 900 percent of the PADI.

Based on a more realistic dietary assessment, using average field trial residues and theoretical percent of crop treated, the estimated average consumption for the U.S. population is 0.00097 mg/kg/day or 32.2 percent of the PADI.

SUMMARY OF REGULATORY POSITION AND RATIONALE

Summary of Agency Position: The Agency is currently evaluating the potential human health risks resulting from the use of mancozeb to determine whether additional regulatory action is warranted on mancozeb and the other EBDC pesticides containing the common contaminant, degradation product, and metabolite, ETU. At this time, the Agency will not establish any new food use tolerances or register any significant new uses. The Agency is also specifying precautionary labeling as set forth below.

Unique Warning Statements Required on Labels:

Manufacturing-Use Products

"This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

End-Use Products

Outdoor Use Products (other than aquatic food and seed treatment)

"This pesticide is toxic to fish. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes."

Seed Treatment Products

"This pesticide is toxic to fish. Cover or incorporate spilled treated seed. Do not contaminate water by cleaning of equipment or disposal of wastes."

Aquatic Food Use Products (cranberry, wild rice, taro)

"This pesticide is toxic to fish. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes."

All Home Use Products

"PROTECTIVE MEASURES: Always spray with your back to the wind. Wear long-sleeve shirt, long pants, and rubber gloves. Wash gloves thoroughly with soap and water before removing. Change your clothes immediately after using this product and launder separately from other laundry items before reuse. Shower immediately after use."

Home Use Products with Food Uses

"Preharvest intervals on this label are specified so that pesticide residues will be at an acceptable level when the crop is harvested."

All Agricultural Products

"After (sprays have dried/dusts have settled/vapors have dispersed, as applicable) do not enter or allow entry into treated areas until the 24-hour reentry interval has expired unless wearing the personal protective equipment listed on the label.

"WORKER SAFETY RULES

"Keep all unprotected persons, children, livestock, and pets away from treated area or where there is danger of drift.

"Do not rub eyes or mouth with hands. See First Aid (Practical Treatment Section).

"PERSONAL PROTECTIVE EQUIPMENT - For Mixers, Loaders, Applicators and Early Reentry Workers.

"HANDLE THIS PRODUCT ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT: a long-sleeve shirt and long pants or a coverall that covers all parts of the body except the head, hands, and feet; chemical resistant gloves; shoes, socks, and goggles or a face shield. During mixing and loading, a chemical resistant apron must also be worn.

"During application from a tractor with a completely enclosed cab with positive pressure filtration, or aerially with an enclosed cockpit, a long-sleeve shirt and long pants may be worn in place of the above protective clothing. Chemical resistant gloves must be available in the cab or cockpit and worn while exiting.

"IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before eating, smoking or drinking. Always wash hands and arms with soap and water before using the toilet.

"After work take off all clothes and shoes. Shower using soap and water. Wear only clean clothes. Do not use contaminated clothing. Wash protective clothing and protective equipment with soap and water after each use. Personal clothing worn during use must be laundered separately from household articles. Clothing and protective equipment heavily contaminated or drenched with mancozeb must be destroyed according to state and local regulations.

"HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

"During aerial application, human flaggers are prohibited unless in totally enclosed vehicles."

SUMMARY OF MAJOR DATA GAPS

<u>Study</u>	<u>Due Date - From Issuance of Standard</u>
Product Chemistry	6-15 months
Residue Chemistry: Plant and animal metabolism Residue studies	18-24 months ^{3/}
Toxicology: Dermal sensitization Subchronic dermal Chronic toxicity (rodent and nonrodent) (mancozeb and ETU) Oncogenicity (rat and mouse) Teratology (rabbit) Reproduction (rat) (mancozeb and ETU) Mutagenicity (mancozeb and ETU) Dermal (percutaneous) absorption (mancozeb and ETU)	9-50 months

^{3/}Dates are determined based on beginning of planting season after issuance of Standard.

<u>Study</u>	<u>Due Date - From Issuance of Standard</u>
Ecological Effects:	9-18 months
Avian dietary	
Avian reproduction	
Estuarine and marine organism	
Fish early life stage	
Aquatic invertebrate life cycle	
Environmental Fate:	9-50 months
Hydrolysis (mancozeb and ETU)	
Photodegradation (mancozeb and ETU)	
Soil metabolism (mancozeb and ETU)	
Aquatic metabolism (mancozeb and ETU)	
Leaching and adsorption/desorption (mancozeb and ETU)	
Volatility	
Degradation (mancozeb and ETU)	
Rotational crops	
Irrigated crops	
Fish accumulation	
Reentry	27 months

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DISCLAIMER: The information presented in this Pesticide Fact Sheet is for information purposes only and may not be used to fulfill data requirements for pesticide registration and reregistration.